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PATENT CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: POONAM SALOTRA, et al.

Serial No.: 10/086,184

Group No.: 1645

Filed: February 27, 2002

Examiner .: --

For: Species-specific PCR Assay for detection of Leishmania Donovani in clinical

samples of Kala-Azar and post Kala-Azar Dermal Leishmaniasis

Attorney Docket No.: U 013891-8

Assistant Commissioner for Patents

Washington, D.C. 20231

Sirs:

SUBSTITUTE DECLARATIONS

Kindly substitute the attached Three Declarations for the documents previously filed on September 25, 2002.

Respectfully submitted

CLIFFORD J. MASS LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NEW YORK 10023 REG. NO. 30,086 (212) 708-1890

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 2023

CLIFFORD J. MASS

(Type of print name of person mailing paper)

Date: December 11, 2002

(Signature of person mailing paper)

Practitioner's Docket No. __

U 013891-8



Optional Customer No. Bar Code

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TECH CENTER 1600/2900



COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

	[x] []	original. design.
NOTE:	declar	he exception of a supplemenial oath or declaration submitted in a reissue, a supplemental oath or ation is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section 5, 7 th Ed.
	[]	supplemental.
NOTE:	lf the a part ap	declaration is for an International Application being filed as a divisional, continuation or continuation-in- oplication, do <u>not</u> check next item; check appropriate one of last three items.
	[]	national stage of PCT.
NOTE:	If one o	of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, INUATION OR C-I-P.
NOTE:	declara	C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application ation in the continuation or divisional application being filed on behalf of the same or fewer of the inventor; in the prior application.
	[]	divisional. continuation.
NOTE:	or divis	an application discloses and claims subject matter not disclosed in the prior application, or a continuation sional application names an inventor not named in the prior application, a continuation-in-part application e filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).
	[]	continuation-in-part (C-I-P).

INVENTORSHIP IDENTIFICATION

WARNING:

If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

		<u>cific PCR Assay for detection of Leishmania Donovani in clinical samples of Kala-Azar</u> la-Azar Dermal Leishmaniasis
-	2001.114	SPECIFICATION IDENTIFICATION
The sp	ecifica	tion of which:
		(complete (a), (b), or (c))
(a)	[]	is attached hereto.
NOTE:	with a	ollowing combinations of information supplied in an oath or declaration filed on the application filing date specification are acceptable as minimums for identifying a specification and compliance with any one of the elow will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:
	declar	"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or ation at the time of execution and submitted with the oath or declaration on filing;
		"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or
		"(3) name of inventor(s), and title which was on the specification as filed."
		Notice of July 13, 1995 (1177 O.G. 60).
(b)	[x]	was filed on February 27, 2002, [x] as Application No. 10/086,184 and was amended on (if applicable).
NOTE:	Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.	
NOTE:	accepto	llowing combinations of information supplied in an oath or declaration filed after the filing date are able as minimums for identifying a specification and compliance with any one of the items below will be a das complying with the identification requirement of 37 C.F.R. Section 1.63: (A) application number (consisting of the series code and the serial number, e.g., 08/123,456); (B) serial number and filing date: (C) attorney docket number which was on the specification as filed: (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration. M.P.E.P. § 601.01(a), 7th ed.

(c)	[]	was o	lescribed and claimed in PCT International Application No		filed
			and as amended under PCT Article 19 on		
		SUP	PLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b)))	
	(complete	e the following where a supplemental declaration is being subm	itted)	
	[]	I here	by declare that the subject matter of the		
		[]	attached amendment amendment filed on		
	was p appli	part of m	y/our invention and was invented before the filing date of the orbove identified, for such invention.	riginal	
	ACI	KNOWI	EDGMENT OF REVIEW OF PAPERS AND DUTY OF CA	ANDOR	
specif	I here	by state includin	that I have reviewed and understand the contents of the above-ig the claims, as amended by any amendment referred to above.	dentified	
37, Co	I acki de of F	nowledge ederal R	e the duty to disclose information, which is material to patentab egulations, Section 1.56,	ility as define	ed in
			(also check the following items, if desired)		
	[]	where	hich is material to the examination of this application, namely, there is a substantial likelihood that a reasonable Examiner wo tant in deciding whether to allow the application to issue as a page	uld consider i	it
		[]	in compliance with this duty, there is attached an information statement, in accordance with 37 C.F.R. Section 1.98.	disclosure	
			PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))		
VOTE:	37 C.F.	R. § 1.55 (Claim for foreign priority.		
		"(a) An foreign and (b).	applicant in a nonprovisonal application may claim the benefit of the filing date applications under the conditions specified in 35 U.S.C. 119(a) through (d) and	of one or more p d (f), 172, and 36	orior 55(a)
			(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim presented during the pendency of the application, and within the later of factual filing date of the application or sixteen months from the fling date	our months fron	n the

having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the

application. This time period is not extendable. The claim must identify the foreign application for which priority os claimed, as well as any foreign application for the same subject matter and

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) (e)	[x] []	no such applications have been filed. such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
			[]YES []NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

(35 U.S.C. Section 119(e))

NOTE: 35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day.

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
/	

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. SECTION 120

[]The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JULIAN H. COHEN, 20302

JOHN RICHARDS, 31053

WILLIAM R. EVANS 25858

RICHARD J. STREIT, 25765

JANET I. CORD, 33778

PETER D. GALLOWAY, 27885

CLIFFORD J. MASS, 30086

RICHARD P. BERG, 28145

CYNTHIA R. MILLER, 34678

(Declaration and Power of Attorney-page 5 of 8) 1-1

(Check the following item, if applicable)

- [] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

NOTE: "Special care should be taken in continuation or divisional applications to ensure that any change of correspondence address in a prior application is reflected in the continuation or divisional application. For example, where a copy of the oath or declaration from the prior application is submitted for a continuation or divisional application filed under 37 CFR 1.53(b) and the copy of the oath or declaration from the prior application designates an old correspondence address, the Office may not recognize, in the continuation or divisional application, the change of correspondence address made during the prosecution of the prior application. Applicant is required to identify the change of correspondence address in the continuation or divisional application to ensure that communications from the Office are mailed to the current correspondence address. 37 CFR 1.63(d)(4)." Section 601.03, M.P.E.P., 7th Ed

SEND CORRESPONDENCE TO

Ladas & Parry 26 West 61st Street New York, N.Y. 10023 DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

Clifford J. Mass (212) 708-1890

(complete the following if applicable)

Since this filing is a [] continuation [] divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

NOTE:	Carefully indicate the fai	mily (or last) name, as it should appear on	the filing r	eceipt and all other document.
NOTE:	Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3).			
NOTE:	~	eparate declarations/oaths provided <u>each</u> cres that a declaration/oath, inter alia, iden this which each sets forth only the name of 17,	nnv each in	venior and promotis inc excession
Full n	ame of sole or first i	nventor		
<u>Poona</u> (Giver	m n Name)	(Middle Initial or Name)		SALOTRA Family (Or Last Name)
Inven	tor's signature (X)	<i></i>		*
Date ((X)	Country of Citizenship	India	
		va Enclave, New Delhi 110017, Inc		
		(Same as above)		
1001			, <u></u>	
				-
	•			·
Full r	name of second joint	inventor, if any		
G. (Give	n Name)	(Middle Initial or Name)		SREENIVAS Family (Or Last Name)
Inver	ntor's signature <u>(X)</u>			
Date	(X)	Country of Citizenship	India	· · · · · · · · · · · · · · · · · · ·
Resid	ience <u>C 145, Sarvoda</u>	<u>ya Enclave, New Delhi 110017, In</u>	dia .	
		ya Enclave, New Delhi 110017, In (Sāmē as above)		
		ya Enclave, New Delhi 110017, In (Same as above)		
Post		(Săffie as above)		
Full Greg	Office Address	(Săffie as above)		
Full Greg (Give	Office Address name of third joint i	(Saffie as above) nventor, if any P.		POGUE
Full Greg (Give	Office Address name of third joint i	(Saffie as above) nventor, if any P.		POGUE Family (Or Last Name)
Full Greg (Give	name of third joint i	(Săifte as above) nventor, if any P (Middle Initial or Name) Country of Citizenship		POGUE Family (Or Last Name)
Full Greg (Give	name of third joint i ory en Name) ntor's signature (X) e (X) // 06.02	(Săifte as above) nventor, if any P (Middle Initial gr Name)		POGUE Family (Or Last Name)

(check proper box(es) for any of the following added page(s) that form a part of this declaration)

[x]	Signature for fourth and subsequent joint inventors. Number of pages addedl
	* * *
[]	Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added
	* * *
[]	Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. Number of pages added
	* * *
[]	Added page for signature by one joint inventor on behalf of deceased inventor(s) where legar representative cannot be appointed in time. (37 C.F.R. Section 1.47)
	* * *
[]	Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application. [] Number of pages added
	* * *
[]	Authorization of practitioner(s) to accept and follow instructions from representative.
	(If no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)
	[] This declaration ends with this page.

PE JOHN SE

ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

a RAMII name of fourth joint inventor, if any

Hiralal (Given Name)	(Middle Initial or Name)	NAKHASI Family (Or Last Name)
Inventor's signature (X)		
	Country of Citizenship	United States of America
	School Terrace, Potomac, Marylan	
•		,
Full name of fifth joint inv	ventor, if any	: ·
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
Date	Country of Citizenship	
Residence		
Post Office Address		
Full name of sixth joint in	ventor, if any	
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature	·	
Residence		
Post Office Address		

U 013891-8

PATENT

Optional Customer No. Bar Code



PATENT TRADEMARK OFFICE

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

original.

design.

(check one applicable item below)

NOTE: With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section 714.16, 7th Ed.

[] supplemental.

[x]

[]

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-inpart application, do <u>not</u> check next item; check appropriate one of last three items.

[] national stage of PCT.

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL. CONTINUATION OR C-I-P.

NOTE: See 37 C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.

[] divisional.
[] continuation.

NOTE: Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).

[] continuation-in-part (C-I-P).

INVENTORSHIP IDENTIFICATION

WARNING:

If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

Spec and p	ies-spec oost Ka	<u>cific PCR Assay for detection of Leishmania Donovani in clinical samples of Kala-Azar</u> la-Azar Dermal Leishmaniasis
-		SPECIFICATION IDENTIFICATION
The sp	ecifica	tion of which:
		(complete (a), (b), or (c))
(a)	[]	is attached hereto.
NOTE:	with a	ollowing combinations of information supplied in an oath or declaration filed on the application filing date specification are acceptable as minimums for identifying a specification and compliance with any one of the velow will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:
	declara	"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or attornation at the time of execution and submitted with the oath or declaration on filing;
		"(2) name of inventor(s), and attorney docket number which was on the specification as filed: or
		"(3) name of inventor(s), and title which was on the specification as filed."
		Notice of July 13, 1995 (1177 O.G. 60).
(b)	[x]	was filed on February 27, 2002, [x] as Application No10/086,184 and was amended on (if applicable).
NOTE:	Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.	
NOTE:	accepta	llowing combinations of information supplied in an oath or declaration filed after the filing date are tible as minimums for identifying a specification and compliance with any one of the items below will be d as complying with the identification requirement of 37 C.F.R. Section 1.63: (A) application number (consisting of the series code and the serial number, e.g., 08/123,456); (B) serial number and filing date; (C) attorney docket number which was on the specification as filed: (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration. M.P.E.P. § 601.01(a), 7th ed.

(c)	[]	was described and claimed in PCT International Application No filed
		on and as amended under PCT Article 19 on (if any).
		SUPPLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))
	(complete the following where a supplemental declaration is being submitted)
	[]	I hereby declare that the subject matter of the
		[] attached amendment [] amendment filed on
	was p applic	art of my/our invention and was invented before the filing date of the original ation, above identified, for such invention.
	ACK	NOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR
specifi	I here cation,	by state that I have reviewed and understand the contents of the above-identified including the claims, as amended by any amendment referred to above.
37, Co	I ackn de of Fe	owledge the duty to disclose information, which is material to patentability as defined in deral Regulations, Section 1.56,
		(also check the following items, if desired)
	[]	and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
		[] in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. Section 1.98.
		PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))
VOTE:	37 C.F.	R. § 1.55 Claim for foreign priority.
		"(a) An applicant in a nonprovisonal application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a) and (b).
		(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the fling date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority os claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) (e)	[]	such applications have been filed.
NOTE:	Where check	item (c) is entered above and the International Application which designated the U.S. itself claimed priority tem (e), enter the details below and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
			[]YES []NO
			[]YES []NO
			[]YES [JNO
			[]YES []NO
			[]YES []NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

(35 U.S.C. Section 119(e))

NOTE: 35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day.

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
/	

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) **UNDER 35 U.S.C. SECTION 120**

[]	The claim for the benefit of any such applications are set forth in the attached
	ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY
	FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P)
	APPLICATION.

ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JULIAN H. COHEN, 20302

JOHN RICHARDS, 31053

WILLIAM R. EVANS 25858

RICHARD J. STREIT, 25765

JANET I. CORD, 33778

PETER D. GALLOWAY, 27885

CLIFFORD J. MASS, 30086

RICHARD P. BERG, 28145

CYNTHIA R. MILLER, 34678

(Declaration and Power of Attorney-page 5 of 8) 1-1

(Check the following item, if applicable)

- [] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

NOTE: "Special care should be taken in continuation or divisional applications to ensure that any change of correspondence address in a prior application is reflected in the continuation or divisional application. For example, where a copy of the oath or declaration from the prior application is submitted for a continuation or divisional application filed under 37 CFR 1.53(b) and the copy of the oath or declaration from the prior application designates an old correspondence address, the Office may not recognize, in the continuation or divisional application, the change of correspondence address made during the prosecution of the prior application. Applicant is required to identify the change of correspondence address in the continuation or divisional application to ensure that communications from the Office are mailed to the current correspondence address. 37 CFR 1.63(d)(4)." Section 601.03, M.P.E.P., 7th Ed

SEND CORRESPONDENCE TO

Ladas & Parry 26 West 61st Street New York, N.Y. 10023 DIRECT TELEPHONE CALLS TO: (Name and telephone number)

Clifford J. Mass (212) 708-1890

(complete the following if applicable)

Since this filing is a [] continuation [] divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

IOTE:	OTE. Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other document					
IOTE:	and at least one given name without					
NOTE:	C .: 1 (2/-1/2) magni	eparate declarations/oaths provided <u>each</u> declard res that a declaration/oath, inter alia, identify ea aths which each sets forth only the name of the ex 97,	ch inventor and promotis the execution of			
Full n	ame of sole or first i	nventor				
D = ====	····		SALOTRA			
Poona (Giver	Name)	(Middle Initial or Name)	Family (Or Last Name)			
Inven	tor's signature (X)	J				
Date (Country of Citizenship Inc	dia			
Resid	ence C 145, Sarvoday	ya Enclave, New Delhi 110017, India				
		(Same as above)	•			
G. (Give Inver Date Resid	lence <u>C 145, Sarvoda</u>	(Middle Initial or Name)				
Greg (Give Inve Date Resi	en Name) ntor's signature (X) e (X)	P. (Middle Initial or Name) Country of Citizenship	POGUE Family (Or Last Name) United States of America			
		., Vacaville, California 95688				
Post		(Same as above)	·			

(check proper box(es) for any of the following added page(s) that form a part of this declaration)

[x]	Signature for fourth and subsequent joint inventors. Number of pages addedl

[]	Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added
	* * *
[]	Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. Number of pages added
	* * *
[]	Added page for signature by one joint inventor on behalf of deceased inventor(s) where lega representative cannot be appointed in time. (37 C.F.R. Section 1.47)
	* * *
[]	Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application. [] Number of pages added
	* * *
[]	Authorization of practitioner(s) to accept and follow instructions from representative.
• :	(If no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)
	[] This declaration ends with this page.

Practitioner's Docket No	<u>U 013891-</u>	8
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ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Full name of fourth joint invo	entor, if any	
Hiralal (Given Name)	(Middle Initial or Name)	NAKHASI Family (Or Last Name)
Inventor's signature (X)	Hudal Nakh	
Date (X) 11/15/62	Country of Citizenship	United States of America
Residence 8504 Potomac Sc	hool Terrace, Potomac, Maryland	20854
Post Office Address	(Same as above)	
· · · · · · · · · · · · · · · · · · ·		
Full name of fifth joint inver	ntor, if any	;
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
Date	Country of Citizenship	<u> </u>
Post Office Address		
	·	:
Full name of sixth joint inve	entor, if any	
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
Date	Country of Citizenship	
Residence		
Post Office Address		
	<u> </u>	

(Added Page to Combined Declaration and Power of Attorney for Signature by Fourth and Subsequent Inventors page 1 of 1) 1-2

EXI This declaration ends with this page.

Jamo Muphy 11/15/2002

Regulatory Counsell, CBER, FDA.



Optional Customer No. Bar Code



PATENT TRADEMARK OFFICE

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

		(check one applicable item below)			
	[x]	original. design.			
NOTE:	OTE: With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Sec. 714.16, 7th Ed.				
	[]	supplemental.			
NOTE:	eclaration is for an International Application being filed as a divisional, continuation or continuation-in- plication, do <u>not</u> check next item; check appropriate one of last three items.				
	[]	national stage of PCT.			
NOTE:	If one of	f the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL. NUATION OR C-I-P.			
NOTE:	declarai	C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application tion in the continuation or divisional application being filed on behalf of the same or fewer of the inventors in the prior application.			
	[]	divisional. continuation.			
VOTE:	or divisi	Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).			
	[]	continuation-in-part (C-I-P).			

INVENTORSHIP IDENTIFICATION

WARNING:

If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

Species-specific PCR Assay for detection of Leishmania Donovani in clinical samples of Kala-Azar

and p	ost Ka	a-Azar Dermal Leishmaniasis
-		SPECIFICATION IDENTIFICATION
The sp	ecificat	tion of which: (complete (a), (b), or (c))
(a)	[]	is attached hereto.
NOTE: "The following combinations of information supplied in an oath or declaration filed on the application with a specification are acceptable as minimums for identifying a specification and compliance with a items below will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.6		
	declara	"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath o ation at the time of execution and submitted with the oath or declaration on filing;
		"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or
		"(3) name of inventor(s), and title which was on the specification as filed."
		Notice of July 13, 1995 (1177 O.G. 60).
(b)	[x] []	was filed on February 27, 2002, [x] as Application No. 10/086,184 and was amended on (if applicable).
NOȚE:	filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not	
NOTE:	encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.	

(c)	[]		lescribed and claimed in PCT International Application No and as amended under PCT Article 19 on	
		OII	and as amended under FCT Afficie 19 on	iy uny).
		SUP	PLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))	
	(complete	e the following where a supplemental declaration is being submitted	t)
	[]	I here	by declare that the subject matter of the	
		[]	attached amendment amendment filed on	
	was p applic	eart of my	y/our invention and was invented before the filing date of the originate bove identified, for such invention.	al
	ACK	NOWL	EDGMENT OF REVIEW OF PAPERS AND DUTY OF CANI	OOR
specif	I here ication,	by state includin	that I have reviewed and understand the contents of the above-ident g the claims, as amended by any amendment referred to above.	tified
37, Cc	I acknode of Fe	owledge ederal R	e the duty to disclose information, which is material to patentability egulations, Section 1.56,	as defined in
			(also check the following items, if desired)	
	[]	where	hich is material to the examination of this application, namely, info there is a substantial likelihood that a reasonable Examiner would tant in deciding whether to allow the application to issue as a patent	consider it
		[]	in compliance with this duty, there is attached an information disc statement, in accordance with 37 C.F.R. Section 1.98.	closure
			PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))	
VOTE:	37 C.F.	R. § 1.55 (Claim for foreign priority.	
		"(a) An o foreign o and (b).	applicant in a nonprovisonal application may claim the benefit of the filing date of o applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f),	ne or more prior 172, and 365(a)
			(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for presented during the pendency of the application,, and within the later of four nactual filing date of the application or sixteen months from the fling date of the application. This time period is not extendable. The claim must identify the foreign which priority os claimed, as well as any foreign application for the same sub	nonths from the ne prior foreign napplication for

having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for agriculty must be made during the

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(e)		such applications have been filed as follows.
NOTE:	Where check	item (c) is entered above and the International Application which designated the U.S. itself claimed priorititem (e), enter the details below and make the priority claim.

(4)

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
			[]YES []NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

(35 U.S.C. Section 119(e))

35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day.

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
/	
	

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) **UNDER 35 U.S.C. SECTION 120**

[] The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), <i>IF ANY,</i> FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JULIAN H. COHEN, 20302

JOHN RICHARDS, 31053

WILLIAM R. EVANS 25858

RICHARD J. STREIT, 25765

JANET I. CORD, 33778

PETER D. GALLOWAY, 27885

CLIFFORD J. MASS, 30086

RICHARD P. BERG, 28145

CYNTHIA R. MILLER, 34678

(Declaration and Power of Attorney-page 5 of 8) 1-1

(Check the following item, if applicable)

- [] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
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SEND CORRESPONDENCE TO

Ladas & Parry 26 West 61st Street New York, N.Y. 10023 DIRECT TELEPHONE CALLS TO: (Name and telephone number)

Clifford J. Mass (212) 708-1890

(complete the following if applicable)

Since this filing is a [] continuation [] divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

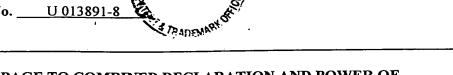
NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other document.

NOTE:	Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3). Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibits the execution separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997,			
NOTE:				
Full n	ame of sole or first i	nventor	,	
Poona (Giver	m n Name)	(Middle Initial or Name)	SALOTRA Family (Or Last Name)	
Inven	tor's signature (X)	. a Pooram		
Date ((X) Wecenboer 5,	2002Country of CitizenshipIr	ndia	
Resid	ence <u>C 145, Sarvoday</u>	a Enclave, New Delhi 110017, India		
Post (Office Address	(Same as above).		
				
	-		· . · .	
Full r	name of second joint	inventor, if any		
	n Name)	(Middle Initial or Name)	SREENIVAS Family (Or Last Name)	
	ntor's signature <u>(X)</u>	* Garage	/	
	·	<u> </u>	ndia	
		ya Enclave, New Delhi 110017, India		
Post	Office Address	(Same as above)		
Full	name of third joint i	nventor, if any		
_		D	POGUE	
Greg (Give	en Name)	(Middle Initial or Name)	Family (Or Last Name)	
Inve	ntor's signature <u>(X)</u>		/	
Date	e (X)	Country of Citizenship	United States of America	
Resi	dence <u>419 Trillick Ct</u>	., Vacaville, California 95688		
Post	Office Address	(Same as above)	· · · · · · · · · · · · · · · · · · ·	

(check proper box(es) for any of the following added page(s) that form a part of this declaration)

[x]	Signature for fourth and subsequent joint inventors. Number of pages addedl
	* * *
[]	Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. <i>Number of pages added</i>
	* * *
[]	Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. Number of pages added
	* * *
[]	Added page for signature by one joint inventor on behalf of deceased inventor(s) where lega representative cannot be appointed in time. (37 C.F.R. Section 1.47)
	* * *
[]	Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application. [] Number of pages added
	* * * .
[]	Authorization of practitioner(s) to accept and follow instructions from representative.
	(If no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)
	[] This declaration ends with this page.

Practitioner's Docket No.	U 013891-
Tractitioner 3 Docker 110.	0 013071



ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Full name of fourth joint in	nventor, if any	
Hiralal (Given Name)	(Middle Initial or Name)	NAKHASI . Family (Or Last Name)
Inventor's signature (X)	<u> </u>	
Date (X)	Country of Citizenship	United States of America
Residence 8504 Potomac	School Terrace, Potomac, Maryland	d 20854
	(Same as above)	
Full name of fifth joint inv	ventor, if any	
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Date	Country of Citizenship	
Residence	· · · · · · · · · · · · · · · · · · ·	
	,	
Full name of sixth joint in	ventor, if any	
	(Middle Initial or Name)	
Inventor's signature		
Residence		
Post Office Address		

(Added Page to Combined Declaration and Power of Attorney for Signature by Fourth and Subsequent Inventors page 1 of 1) 1-2